

SEP 15 2000

K 001842

SOMANETICS INVOS 5100 CEREBRAL OXIMETER 510(K) PREMARKET NOTIFICATION

Section 9

510(k) Summary

1. **Date Prepared:** 6/16/2000
2. **Submitter/Contact:** Ronald A. Widman
Vice President, Medical Affairs
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083
Phone: (248) 689-3050
Fax: (248) 689-4272
3. **Trade Name:** Somanetics INVOS® 5100 Adult/Pediatric Cerebral Oximeter for use with:
INVOS® 5100-SSP and 5100-SPF Pediatric SomaSensor® intended for use with children who weigh between 4 and 40 kg (8.8 to 88 lbs.).
INVOS® 4100-SSA and 4100-SPF SomaSensor® intended for use with adults or children over 40 kg.
Accessories:

5100-P	Spare Preamplifier Cable
5100-W	One-year Extension of Warranty
5100-M	Spare 5100 System Operations Manual
5100-FTD	Field Test Device
4100-BRC	Spare Bilateral Reusable Sensor Cable
4100-STD	Portable Mobile Stand
4100-TC	Travel Case
4100-PC	Spare Power Cord
DB9DB9	Computer Connection Serial Cable
4100-DPU-414	Thermal Printer w/ 10' Cable
312109	Thermal Paper
4100-DD	3.5" Floppy Disk Drive
4. **Classification Name:** Oximeters
5. **Common Name:** Cerebral Oximeter
6. **Regulatory Class:** Oximeters have been classified in Class II by the Cardiovascular device panel, see 21 CFR 870.2700.
7. **Performance Stds:** FDA has not developed performance standards for this device. Also, oximeters have not been assigned any special controls.

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individual. Because INVOS values are relative within an individual, the INVOS should not be used as the sole basis for decisions as to diagnosis or therapy. The value of data from the INVOS has not been demonstrated in disease states.

Contraindications: None.

9. Device Description:

The principles of operation of the cerebral oximeter system are based on the assumption that hemoglobin exists in two principal forms in the blood: oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb). Functional oxygen saturation (SO_2) is defined as the ratio of oxyhemoglobin (HbO_2) to total hemoglobin ($\text{HbO}_2 + \text{Hb}$) and is commonly presented as a percentage.

$$\text{SO}_2 = \frac{\text{HbO}_2}{\text{HbO}_2 + \text{Hb}} \times 100\%$$

Since oxygenated and reduced hemoglobin are different colors and absorb light as a known function of wavelength, selected wavelengths of light can be used to assess the relative percentage of these two constituents. This fundamental approach of assessing the color of blood using various wavelengths of light to measure hemoglobin oxygen saturation trends is used in all currently marketed oximetry systems.

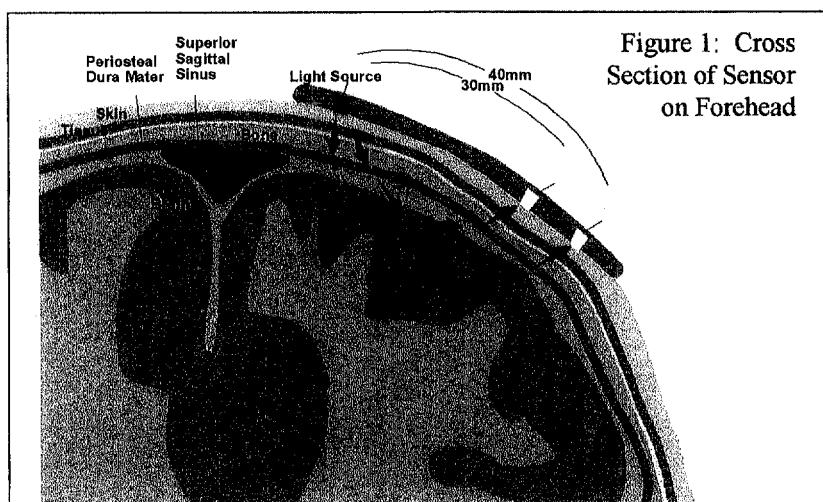


Figure 1: Cross Section of Sensor on Forehead

A disposable sensor of medical grade materials is applied to the patient's forehead (Figure 1). The sensor incorporates a light source and two return signal detectors at different pre-determined distances from the light source. The signal detector nearest the light source (3 cm) is considered the "shallow detector" and the further detector from the light source (4 cm) the "deep detector."

While the light reaching the deep detector has sampled about the same amount of skin, scalp, and skull as the light reaching the shallow detector, it has sampled more brain tissue. This difference is used to help separate out the brain signal and suppress anatomical differences in patients. The additional information unique to the deep signal return is predominately from brain tissue blood which is composed mostly of venous blood. The information contained in the shallow and deep signal returns is processed by an algorithm to measure changes in hemoglobin oxygen saturation in a small region of tissue beneath the sensor, predominately in the brain.

The SomaSensor is connected to a preamplifier (1.4 x 7.65 x 3.75 in.) which is placed close to the patient and amplifies the rSO_2 signal. The signal is then carried to a display unit (8.4 x 9.6 x 8.5 in.) where the values and trends are displayed on the screen. The display unit controls all functions of the system with selections made by keys with on-screen labels. The system will operate for up to 30 minutes on battery, enabling patient transport without loss of data.

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8.5 in.) where the values and trends are displayed on the screen. The display unit controls all functions of the system with selections made by keys with on-screen labels. The system will operate for up to 30 minutes on battery, enabling patient transport without loss of data.

10. **Substantial Equivalence:**

The INVOS 5100 is substantially equivalent to the modified INVOS 3100A (K971628) in that the method of measurement and physical configuration are identical but the indications for use are expanded. The newer INVOS 5100 will operate with either the INVOS 5100-SSP or 5100-SPF Pediatric SomaSensor to monitor pediatric patients between 4 and 40 kg, or the INVOS 4100-SSA or 4100-SAF Adult SomaSensor for adults.

11. **Nonclinical Testing:**

The INVOS 5100 Adult/Pediatric Cerebral Oximeter System and the 5100-SSP and 5100-SPF Pediatric SomaSensors have been tested in accordance with Design Validation Documents V99-004 Application Software Validation for INVOS 5100 Cerebral Oximeter and V99-005 INVOS 5100 Design Validation documents. The result of the validations confirms that the model 5100 is substantially equivalent to the predicate model 4100.

12. **Clinical Testing:**

Clinical data on pediatric subjects was collected in the pediatric cardiac cath lab at Children's Hospital in Pittsburgh, PA. Investigators were Steven Webber, MD (PI), Jose Ettedgui, MD and Edwin Nemoto, PhD. Like the adult volunteer hypoxia study (K971628), cerebral oximetry values were compared to arterial and jugular venous blood oxygen saturations combined in a 1:3 ratio, as analyzed by a co-oximeter. Since human brain tissue is assumed to contain 75% venous blood by volume, this combination of blood oxygen saturations approximates the oxygen saturation in the capillaries in the area of the cerebral oximetry sensor. However, unlike the adult study, the subjects were pediatric patients with congenital malformations of the heart and large vessels. In this population, it was ethically inappropriate to manipulate oxygen or carbon dioxide levels in the subject's blood. Therefore, data was simply collected during different periods of the catheterization case at normal and elevated levels of oxygen (using oxygen blow-by technique).

Twenty-two subjects completed the study with recorded data. At least five samples were drawn per subject at various times during the cath procedure. Agreement between individual and pooled oximetry data and blood samples was as good or better than agreement for the adult sensor, both for absolute data and transition (trend) data. The study results support the substantial equivalence of the INVOS 5100 Adult/Pediatric Cerebral Oximeter with the INVOS 4100 Adult Cerebral Oximeter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 15 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ronald A. Widman
Somanetics Corporation
1653 East Maple Road
Troy, MI 48083-4208

Re: K001842
Somanetics Invos® 5100 Adult/Pediatric Cerebral Oximeter and 5100
SSP and 5100 SPF Pediatric SomaSensor®
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: June 16, 2000
Received: June 19, 2000

Dear Mr. Widman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

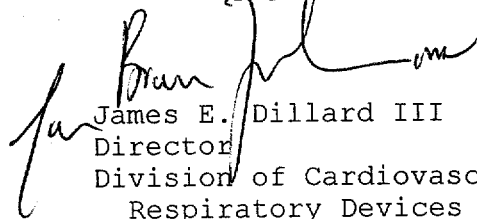
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in dark ink, appearing to read "James E. Dillard III", is written over the typed name and title.

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K001842


Somanetics INVOS® 5100 Adult/Pediatric Cerebral Oximeter and 5100-
Device Name: SSP and 5100-SPF Pediatric SomaSensor®

Indications For Use:

The noninvasive INVOS 5100 Adult/Pediatric Cerebral Oximeter should be used as an adjunct monitor of trends in regional hemoglobin oxygen saturation of blood in the brain of an individual. Because INVOS values are relative within an individual, the INVOS should not be used as the sole basis for decisions as to diagnosis or therapy. The value of data from the INVOS has not been demonstrated in disease states.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for 
Division of Cardiovascular & Respiratory Devices
510(k) Number K001842

Prescription Use 1
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)